25 TEXAS ADMINISTRATIVE CODE

§289.301

Registration and Radiation Safety Requirements for Lasers

Texas Regulations for Control of Laser Radiation Hazards

(effective February 14, 1999)

§289.301. Registration and Radiation Safety Requirements for Lasers.

(a) Purpose.

(1) This section establishes requirements for the registration of persons who receive, possess, acquire, transfer, or use class IIIb and class IV lasers in the healing arts, veterinary medicine, industry, academic, research and development institutions, and of persons who are in the business of providing laser services. No person shall use lasers or perform laser services except as authorized in a certificate of laser registration issued by the agency in accordance with the requirements of this section.

(2) This section also establishes requirements for protection against laser radiation hazards resulting from activities conducted with class IIIb or class IV lasers. This section includes responsibilities of the registrant and the laser safety officer (LSO), laser hazard control methods, training requirements and notification of injuries.

(b) Scope.

(1) Except as otherwise specifically provided, this section applies to all persons who receive, possess, acquire, transfer, or use lasers that emit or may emit laser radiation. Nothing in this section shall be interpreted as limiting the intentional exposure of patients to laser radiation for the purpose of diagnosis, therapy, or treatment by a licensed practitioner of the healing arts. Individuals shall not use lasers on humans for medical or cosmetic purposes unless under the supervision of a licensed practitioner of the healing arts. This chapter does not apply to the manufacture of lasers.

(2) Lasers, including lasers used on humans for research demonstration, shall meet the requirements of any applicable federal standards in 21 Code of Federal Regulations (CFR) 1040. All lasers shall meet the requirements of these and any other applicable state requirements.

(3) If any conflict arises between the requirements of this section and the laser performance standards in 21 CFR 1040, the requirements of the federal standard shall apply.

(4) This section applies to lasers that operate at wavelengths between 180 nanometers (nm) and 1 millimeter (mm).

(5) In addition to the requirements of this section, all registrants are subject to the applicable requirements of §289.112 of this title (relating to Hearing and Enforcement Procedures); §289.201 of this title (relating to General Provisions); §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections); and §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material(s) Licenses, Emergency Planning and Implementation, and Other Regulatory Services).

(c) Prohibitions.

(1) The agency may prohibit uses of lasers that pose significant threat or endanger public health and safety, in accordance with §289.112 of this title and §289.201 of this title.

(2) Individuals shall not be intentionally exposed to laser radiation unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

(A) exposure of an individual for training, demonstration, or other non-healing arts purposes;

(B) exposure of an individual for the purpose of healing arts screening, except as specifically authorized by the agency; and

(C) exposure of an individual for the purpose of research. Any research using radiation producing devices on humans must be approved by an institutional review board (IRB) as required by 45 Code of Federal Regulations (CFR) 46 and 21 CFR 56. The IRB must include at least one practitioner of the healing arts to direct use of laser radiation in accordance with subsection (b)(1) of this section.

(d) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Accessible emission limit (AEL) - The maximum accessible emission level permitted within a particular class.

(2) α_{max} - The angular limit beyond which extended source maximum permissible exposures (MPE) for a given exposure duration are expressed as a constant radiance or integrated radiance. This value is defined as 100 milliradians.

(3) α_{min} - (See definition for limiting angular subtense.)

(4) Aperture - An opening through which radiation can pass.

(5) Apparent visual angle - The angular subtense of the source as calculated from source size and distance from the eye. It is not the beam divergence of the source.

(6) Attenuation - The decrease in the radiant flux of any optical beam as it passes through an absorbing or scattering medium.

(7) Beam - A collection of rays that may be parallel, divergent, or convergent.

(8) C_A - Correction factor that increases the MPE values in the near infrared (IR-A) spectral band (700-1400 nm) based upon reduced absorption properties of melanin pigment granules found in the skin and in the retinal pigment epithelium.

(9) C_B - Correction factor that increases the MPE values in the red end of the visible spectrum (550-700 nm) because of greatly reduced photochemical hazards.

(10) C_C - Correction factor that increases the MPE values for ocular exposure because of pre-retinal absorption of radiant energy in the spectral region between 1150 and 1400 nm.

(11) C_E - Correction factor used for calculating the extended source MPE for the eye from the intrabeam MPE, when the laser source subtends a visual angle exceeding α_{min}.

(12) C_F - Correction factor that reduces the MPE for repetitively pulsed exposure of the eye.

(13) Class I laser - Any laser that does not permit access during the operation to levels of laser radiation in excess of the accessible emission limits contained in subsection (cc)(1) of this section.

(14) Class II laser - Any laser that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits contained in subsection (cc)(1) of this section, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in subsection (cc)(2) of this section.

(15) Class IIIa laser - Any laser that permits human access during operation to levels of visible laser radiation in excess of the accessible emission limits contained in subsection (cc)(2) of this section, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in subsection (cc)(3) of this section.

(16) Class IIIb laser - Any laser that permits human access during operation to levels of laser radiation in excess of the accessible emission limits of subsection (cc)(3) of this section, but does not permit human access during operation to levels of laser radiation in excess of the accessible emission limits contained in subsection (cc)(4) of this section.

(17) Class IV laser - Any laser that permits human access during operation to levels of laser radiation in excess of the accessible emission limits contained in subsection (cc)(4) of this section.

(18) Coherent - A light beam is said to be coherent when the electric vector at any point in it is related to that at any other point by a definite, continuous function.

(19) Collateral radiation - Any electromagnetic radiation, except laser radiation, emitted by a laser that is physically necessary for its operation.

(20) Collimated beam - Effectively, a "parallel" beam of light with very low divergence or convergence. (See definition for intrabeam viewing.)

(21) Continuous wave (CW) - The output of a laser that is operated in a continuous rather than a pulsed mode. In this section, a laser operating with a continuous output for a period of $\geq$0.25 seconds is regarded as a CW laser.

(22) Controlled area - An area where the occupancy and activity of those within is subject to control and supervision by the registrant for the purpose of protection from radiation hazards.

(23) Cosmetic - Radiation intended to be applied to the human body or any part of the human body for cleaning, beautifying, promoting attractiveness, or altering the appearance.

(24) Diopter - A measure of the power of a lens, defined as $1/f_0$, where f_0 is the focal length of the lens in meters.

(25) Divergence - For purposes of this section, divergence is taken as the full angle, expressed in radian, of the beam spread measured between those points that include laser energy or irradiance equal to 1/e (where e means base natural logarithm) of the maximum value (the angular extent of a beam that contains all the radius vectors of the polar curve of radiant intensity that have length rated at 36.8% of the maximum). This is also referred to as beam spread.

(26) Electromagnetic radiation - The flow of energy consisting of orthogonally vibrating electric and magnetic fields lying transverse to the direction of propagation. X-ray, ultraviolet, visible, infrared, and radio waves occupy various portions of the electromagnetic spectrum and differ only in frequency, wavelength, or photon energy.

(27) Electronic product - Any product or article defined as follows:

(A) any manufactured or assembled product that, when in operation:

(*i*) contains or acts as part of an electronic circuit; and

(*ii*) emits, or in the absence of effective shielding or other controls would emit, electronic product radiation; or

(B) any manufactured or assembled article that is intended for use as a component, part, or accessory of a product described in subparagraph (A) of this paragraph and that when in operation emits, or in the absence of effective shielding or other controls would emit, such radiation.

(28) Energy - The capacity for doing work. Energy content is commonly used to characterize the output from pulsed lasers, and is generally expressed in joules (J).

(29) Entertainment laser - Any laser manufactured, designed, intended, or promoted for purposes of entertainment, advertising display, or artistic composition.

(30) Focal point - The point toward which radiation converges or from which radiation diverges or appears to diverge.

(31) Hertz (Hz) - The unit that expresses the frequency of a periodic oscillation in cycles per second.

(32) Infrared radiation - Electromagnetic radiation with wavelengths that lie within the range 700 nm to 1 mm.

(33) Institutional Review Board (IRB) - Any board, committee, or other group formally designated by an institution to review, approve the initiation of, and conduct periodic review of biomedical research involving human subjects.

(34) Intrabeam viewing - The viewing condition where the source subtends an angle at the eye that is equal to or less than α_{min}, the limiting angular subtense. This category includes most collimated beams and so called point sources.

(35) Irradiance (at a point of a surface) - The quotient of the radiant flux incident on an element of the surface containing the point at which irradiance is measured, by the area of that element. Unit: watt per square centimeter (W/cm^{-2}).

(36) Joule - A unit of energy. One joule is equal to one watt • second.

(37) Laser - A device that produces an intense, coherent, directional beam of light by stimulating electronic or molecular transitions to lower energy levels. "Laser" is an acronym for light amplification by stimulated emission of radiation. The term "laser" also includes the assembly of electrical, mechanical, and optical components associated with the laser.

(38) Laser product - Any manufactured product or assemblage of components that constitutes, incorporates, or is intended to incorporate a laser and is classified as a class I, II, IIIa, IIIb or IV laser product according to the performance standards set by the United States Food and Drug Administration (FDA). A laser that is intended for use as a component of an electronic product shall itself be considered a laser product. A laser product contains an enclosed laser with an assigned class number higher than the inherent capability of the laser in which it is incorporated and where the product's lower classification is appropriate due to the engineering features limiting accessible emission.

(39) Laser safety officer - An individual who has a knowledge of and the authority and responsibility to apply appropriate laser radiation protection rules, standards, and practices, and who must be specifically authorized on a certificate of laser registration.

(40) Limiting angular subtense (α_{min}) - The apparent visual angle that divides intrabeam viewing from extended-source viewing.

(41) Limiting aperture (D_r) - The maximum diameter of a circle over which irradiance and radiant exposure can be averaged.

(42) Limiting exposure duration (T_{max}) - An exposure duration that is specifically limited by the design or intended use(s).

(43) Maximum permissible exposure (MPE) - The level of laser radiation to which a person may be exposed without hazardous effect or adverse biological changes in the eye or skin.

(44) Medical event - Any adverse patient health effect that is a result of failure or misuse of a laser safety equipment.

(45) Nominal hazard zone (NHZ) - The space within which the level of direct, reflected, or scattered radiation during operation exceeds the applicable MPE. Exposure levels beyond the boundary of the NHZ are below the applicable MPE level.

(46) Optical density (D_λ) - The logarithm to the base ten of the reciprocal of the transmittance. $D_\lambda = -\log_{10} \tau_\lambda$, where τ_λ is transmittance.

(47) Point source - A source of radiation whose dimensions are small enough to result in a subtended angle that is less than α_{min}. For the purpose of this section, a point source leads to intrabeam viewing condition.

(48) Practitioner of the healing arts (practitioner) - A person licensed to practice the healing arts by either the Texas State Board of Medical Examiners as a physician; the Texas State Board of Dental Examiners; the Texas Board of Chiropractic Examiners; or the Texas State Board of Podiatry Examiners.

(49) Protective housing - An enclosure surrounding the laser that prevents access to laser radiation above the applicable MPE level. The aperture through which the useful beam is emitted is not part of the protective housing. The protective housing may enclose associated optics and a work station and shall limit access to other associated radiant energy emissions and to electrical hazards associated with components and terminals.

(50) Provider of lasers - A person who furnishes a laser(s) on a routine basis for a limited time period to a facility(ies) that operates the laser(s) during that limited time period.

(51) Pulse duration - The duration of a laser pulse. This is usually measured as the time interval between the half-power points on the leading and trailing edges of the laser pulse.

(52) Pulsed laser - A laser that delivers its energy in the form of a single pulse or a train of pulses. In this section, the duration of a pulse is <0.25 seconds in a pulsed laser.

(53) Reflection - The deviation of radiation following incidence on a surface.

(54) Service - The performance of those procedures or adjustments described in the manufacturer's service instructions that may affect any aspect of the performance of the laser.

(55) Source - A laser or a laser-illuminated reflecting surface.

(56) T_1 - The exposure duration (time) at which MPEs based upon thermal injury are replaced by MPEs based upon photochemical injury to the retina.

(57) T_{max} - (See definition for limiting exposure duration.)

(58) Transmission - Passage of radiation through a medium.

(59) Ultraviolet radiation - Electromagnetic radiation with wavelengths smaller than those of visible radiation; for the purpose of this section 180 to 400 nm.

(60) Visible radiation (light) - Electromagnetic radiation that can be detected by the human eye. This term is commonly used to describe wavelengths that lie in the range of 400 to 700 nm.

(61) Watt - The unit of power or radiant flux. 1 watt equals 1 joule per second.

(62) Wavelength (λ) - The distance between two successive points on a periodic wave that have the same phase.

(e) Exemptions.

(1) Lasers in transit or in storage incident to transit are exempt from the requirements of this section. This exemption does not apply to the providers of lasers.

(2) Inoperable lasers are exempt from the requirements of this section.

(3) Class I, class II, and class IIIa lasers or products are exempt from the requirements of this section.

(4) Class III mobile lasers are exempt from registration only if they are continuous wave (CW) in the wavelength range of $400 < \lambda \leq 700$ nm and have a peak radiant power of less than or equal to 5×10^{-3} watts.

(f) Registration of laser uses and services.

(1) For purposes of this section, laser uses and services shall include, but may not be limited to:

(A) possession and use of lasers in the healing arts, veterinary medicine, industry, academic, and research and development institutions;

(B) demonstration and sales of lasers that require the individual to operate or cause a laser to be operated in order to demonstrate or sell;

(C) provision of lasers on a periodic basis to a facility for limited time periods by a provider of lasers;

(D) alignment, calibration, and/or repair; or

(E) laser light shows.

(2) A person who has made application for registration in accordance with this section and is using a laser prior to receiving a certificate of laser registration is subject to the requirements of this chapter.

(g) Application requirements.

(1) General application requirements.

(A) Application for certificate of laser registration shall be completed on forms prescribed by the agency and shall contain all the information required by the form and accompanying instructions.

(B) A laser safety officer (LSO) shall be designated on each application form. The qualifications of that individual shall be submitted to the agency with the application. The LSO shall meet the applicable requirements of subsection (p) of this section and carry out the responsibilities of subsection (q) of this section.

(C) If the applicant is a corporation under the Texas Business Corporation Act, BRC Form 226-1 shall be submitted with the application to confirm that no tax owed the state under Tax Code, Chapter 171, is delinquent.

(D) Each application for a certificate of laser registration shall be accompanied by the appropriate fee prescribed in §289.204 of this title.

(E) An application for a certificate of laser registration may include a request for a certificate of laser registration authorizing one or more activities.

(F) The agency may, at any time after filing of the original application and before issuance of the certificate of registration, require further statements in order to enable the agency to determine whether the application should be granted or denied.

(G) Applications and documents submitted to the agency may be made available for public inspection except that the agency may withhold any document or part thereof from public inspection in accordance with §289.201(n) of this title.

(2) Application for use of laser on humans or animals.

(A) In addition to the requirements of subsection (g)(1) of this section, each person having a laser for use in the healing arts, or for use on animals shall submit an application to the agency within 30 days following the commencement of operation of that laser.

(B) An application for healing arts shall be signed by a licensed practitioner of the healing arts. An application for veterinary medicine shall be signed by a veterinarian. The signature of the administrator, president, or chief executive officer will be accepted in lieu of a licensed practitioner's signature if the facility is a licensed hospital or a medical facility. A signature by the administrator, president, or chief executive officer does not relieve the practitioner user or veterinarian user from complying with the requirements of this section.

(C) If a person is furnished a laser by a provider of lasers, that person is responsible for ensuring that a licensed practitioner of the healing arts authorizes intentional exposure of laser radiation to humans.

(3) Application for use of lasers in industrial, academic, and research and development institutions. In addition to the requirements of subsection (g)(1) of this section, each applicant having a laser(s) for use in industrial, academic, and research and development institutions shall submit an application to the agency within 30 days following the commencement of operation.

(4) Application for demonstration for the purpose of sales of lasers.

(A) Each applicant shall apply for and receive a certificate of laser registration before the demonstration for purpose of selling laser(s), including demonstration for the selling of surplus lasers.

(B) In addition to the requirements of subsection (g)(1) of this section, the applicant shall submit a statement confirming that no demonstration will be performed on humans unless directed by a licensed practitioner of the healing arts.

(5) Application for providers of lasers.

(A) Each applicant shall apply for and receive a certificate of laser registration before providing lasers.

(B) In addition to the requirements of subsection (g)(1) of this section, the applicant shall submit the following:

(*i*) the address of the established main location where the laser and records will be maintained for inspection. This shall be a physical street address, not a post office box number; and

(*ii*) a list of facilities where the laser will be provided.

(6) Application for alignment, calibration, and/or repair. In addition to the requirements of subsection (g)(1) of this section, each applicant shall apply for and receive a certificate of laser radiation for alignment, calibration, and/or repair before providing alignment, calibration, and/or repair of lasers.

(7) Application for laser light show.

(A) Each applicant shall apply for and receive a certificate of laser registration for laser light show before beginning any show.

(B) In accordance with subparagraph (A) of this paragraph and in addition to the requirements of subsection (g)(1) of this section, each applicant shall submit the following:

(*i*) a valid variance issued from the FDA for the laser intended to be used. The registrant shall comply with the conditions of the FDA variance.

(*ii*) a written notice of the laser light show to be performed in Texas. The information contained in BRC Form 301-3 shall be provided seven days prior to each show. If, in a specific case the seven working-day period would impose an undue hardship on the applicant, the applicant may, upon written request to the agency, obtain permission to proceed sooner.

(8) Application for mobile services used in the healing arts and veterinary arts.

(A) Each applicant shall apply for and receive a certificate of laser registration for mobile services before beginning to provide mobile services.

(B) In addition to the requirements of subsection (g)(1) of this section, each applicant shall submit the address of the established main location where the laser, records, etc. will be maintained for inspection. This shall be a physical street address, not a post office box number.

(C) An application for mobile services for healing arts shall be signed by a licensed practitioner of the healing arts and an application for mobile services for veterinary medicine shall be signed by a veterinarian.

(h) Issuance of certificate of laser registration.

(1) Upon determination that an application meets the requirements of the Texas Radiation Control Act (Act) and the rules of the agency, the agency may issue a certificate of laser registration authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(2) The agency may incorporate in the certificate of laser registration at the time of issuance, or thereafter by amendment, such additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of lasers subject to this section as it deems appropriate or necessary in order to:

(A) minimize danger to public health and safety;

(B) require such reports and the keeping of such records for inspection by the agency; and

(C) prevent loss or theft of lasers subject to this section.

(i) Specific terms and conditions of certificates of laser registration.

(1) Each certificate of laser registration issued in accordance with this section shall be subject to the applicable provisions of the Act, now or hereafter in effect, and to the applicable rules in this chapter and orders issued by the agency.

(2) Each person registered by the agency for laser use in accordance with this section shall confine use and possession of the laser registered to the locations and purposes authorized in the certificate.

(3) No certificate of laser registration issued or granted under this section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, to any person unless the agency authorizes the transfer in writing.

(j) Responsibilities of registrant.

(1) The registrant shall notify the agency in writing within 30 days of a change in any of the following:

(A) name and mailing address;

(B) laser safety officer (LSO); or

(C) name of facility contracted for "provider of services", if applicable.

(2) No person shall make, sell, lease, transfer, or lend lasers unless such machines and equipment, when properly placed in operation and used, meet the applicable requirements of this section.

(3) When requested by the agency, the registrant shall submit an inventory of lasers possessed and used, including disposition.

(4) The mobile service company providing mobile services shall provide evidence of registration with the agency to each facility receiving the services.

(5) The registrant is responsible for complying with this section and the conditions of the certificate of laser registration.

(k) Expiration of certificates of laser registration.

(1) Except as provided by subsection (m) of this section, each certificate of laser registration that specifies an expiration date expires at the end of the day on that date. Expiration of the certificate of laser registration does not relieve the registrant of the requirements of this chapter.

(2) If a registrant does not submit an application for renewal of the certificate of laser registration under subsection (m) of this section, as applicable, the registrant shall on or before the expiration date specified in the certificate of laser registration terminate use and/or services of laser(s) and request termination as outlined in subsection (l) of this section.

(l) Termination of certificates of laser registration.

(1) Each registrant shall notify the agency immediately, in writing, and request termination of the certificate of laser registration when the registrant decides to terminate all activities involving lasers authorized under the certificate of laser registration.

(2) Concurrent with the notification and request for termination of the certificate of laser registration, the registrant shall do the following:

(A) submit a record of disposal of lasers; and

(B) pay any outstanding fees in accordance with §289.204 of this title.

(m) Renewal of certificate of registration.

(1) Application for renewal of laser registration shall be filed in accordance with subsection (g) of this section.

(2) If a registrant files an application in proper form before the existing certificate of laser registration expires, such existing certificate of laser registration shall not expire until the application status has been determined by the agency.

(n) Modification and revocation of certificates of laser registration. Modification, suspension, and revocation of certificates of laser registration shall be in accordance with §289.205 of this title.

(o) Notifications.

(1) Each registrant shall notify the agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy by or against:

(A) a registrant;

(B) an entity controlling a registrant or listing the certificate of laser registration of the registrant as property of the estate; or

(C) an affiliate of the registrant.

(2) This notification shall include:

(A) the bankruptcy court in which the petition for bankruptcy was filed;

(B) the name of the entity in bankruptcy; and

(C) the date of the filing of the petition.

(3) A copy of the "petition for bankruptcy" shall be submitted to the agency along with the written notification.

(p) LSO qualifications. LSO qualifications shall be submitted to the agency and shall include the following:

(1) educational courses related to laser radiation safety or a laser safety officer course; or

(2) experience in the use and familiarity of the type of equipment or services registered for; and

(3) knowledge of potential laser radiation hazards and laser emergency situations.

(q) LSO duties. Specific duties of the LSO shall include, but not be limited to the following:

(1) ensuring that users of lasers are trained in laser safety, as applicable for the class and type of lasers the individual uses;

(2) assuming control and having the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions; and

(3) specifying whether any changes in control measures are required following:

(A) any service and maintenance of lasers that may affect the output power or operating characteristics; or

(B) whenever deliberate modifications are made that could change the laser class and affect the output power or operating characteristics.

(4) ensuring maintenance and other practices required for safe operation of the laser(s) are performed;

(5) ensuring the proper use of protective eyewear and other safety measures; and

(6) ensuring compliance with the requirements in this section and with any engineering or operational controls specified by the registrant.

(r) Requirements for protection against laser radiation. These requirements are for lasers in their intended mode of operation and include special requirements for service, testing, maintenance, and modification. During some laser operations, certain engineering controls may be inappropriate. In situations where an engineering control may be inappropriate, for example, during medical procedures or surgery, the LSO shall specify alternate controls to obtain equivalent laser safety protection.

(1) MPE. Each registrant or user of any laser shall not permit any individual to be exposed to levels of laser or collateral radiation higher than are specified in subsection (cc)(5)-(8) of this section.

(2) Engineering controls.

(A) Protective housing.

(*i*) Each laser shall have a protective housing that prevents human access during the operation of the laser and collateral radiation that exceeds the limits of class I and subsection (cc)(8)(A) and (B) of this section, wherever and whenever such human access is not necessary in order for the laser to perform its intended function.

(*ii*) Wherever and whenever human access to laser radiation levels that exceed the limits of class I and subsection (cc)(8)(A) and (B) of this section is necessary, these levels shall not exceed the limits of the lowest laser class necessary to perform the intended function(s).

(B) Safety interlocks.

(*i*) A safety interlock, that shall ensure that radiation is not accessible above MPE limits, shall be provided for any portion of the protective housing that by design can be removed or displaced without the use of tools during normal operation or maintenance, and thereby allows access to radiation above MPE limits.

(*ii*) Adjustment during operation, service, testing, or maintenance of a laser containing interlocks shall not cause the interlocks to become inoperative or the radiation to exceed MPE limits outside protective housing except where a laser controlled area as specified in subparagraph (E) of this paragraph is established.

(*iii*) For pulsed lasers, interlocks shall be designed so as to prevent firing of the laser; for example, by dumping the stored energy into a dummy load.

(*iv*) For CW lasers, the interlocks shall turn off the power supply or interrupt the beam; for example, by means of shutters.

(*v*) An interlock shall not allow automatic accessibility of radiation emission above MPE limits when the interlock is closed.

(*vi*) Either multiple safety interlocks or a means to preclude removal or displacement of the interlocked portion of the protective housing upon interlock failure shall be provided, if failure of a single interlock would allow the following:

(I) human access to levels of laser radiation in excess of the radiant power accessible emission limit of class IIIa laser radiation; or

(II) laser radiation in excess of the accessible emission limits of class II to be emitted directly through the opening created by removal or displacement of that portion of the protective housing.

(C) Viewing optics and windows.

(*i*) All viewing ports, viewing optics, or display screens included as an integral part of an enclosed laser or laser shall incorporate suitable means to attenuate the laser and collateral radiation transmitted through the port to less than the MPE and the limits listed in subsection (cc)(8) of this section under any conditions of operation of the laser.

(*ii*) Since optical systems such as lenses, telescopes, and microscopes may increase the hazard to the eye or the skin, the potential hazard and specific administrative procedures and the use of controls such as interlocks or filters shall be determined.

(D) Warning systems. Each class IIIb or IV laser or laser product shall provide visual or audible indication during the emission of accessible laser radiation. In the case of class IIIb lasers, except those that allow access only to less than 5 milliwatt (mW) peak visible laser radiation, and class IV lasers, this indication shall be sufficient prior to emission of such radiation to allow appropriate action to avoid exposure. Any visual indicator shall be clearly visible through protective eyewear designed specifically for the wavelength(s) of the emitted laser radiation. If the laser and laser energy source are housed separately and can be operated at a separation distance of greater than two meters, both laser and laser energy source shall incorporate visual or audible indicators. The visual indicators shall be positioned so that viewing does not require human access to laser radiation in excess of the MPE.

(E) Controlled area. With a class IIIb laser, except those that allow access only to less than 5 mW visible peak power, or class IV laser, a controlled area shall be established when exposure to the laser radiation in excess of the MPE or the limits listed in subsection (cc)(8) of this section is possible. The controlled area shall meet the following requirements, as applicable.

(*i*) The area shall be posted as required by subsection (v) of this section.

(*ii*) Access to the controlled area shall be restricted.

(*iii*) For class IV indoor controlled areas, latches, interlocks, or other appropriate means shall be used to prevent unauthorized entry into controlled areas.

(I) Such measures shall be designed to allow rapid egress by the laser personnel at all times and admittance to the controlled area in an emergency condition. For such emergency conditions, a control-disconnect switch or equivalent device (panic button) shall be available for deactivating the laser.

(II) Where safety latches or interlocks are not feasible or are inappropriate, for example during medical procedures, such as surgery, the following shall apply.

(-a-) All authorized personnel shall be trained in laser safety and appropriate personal protective equipment shall be provided upon entry.

(-b-) A door, blocking barrier, screen, or curtains shall be used to block, screen, or attenuate the laser radiation at the entryway. The level at the exterior of these devices shall not exceed the applicable MPE, nor shall personnel experience any exposure above the MPE immediately upon entry.

(-c-) At the entryway there shall be a visible or audible signal indicating that the laser is energized and operating at class IV levels. A lighted laser warning sign, flashing light (visible through laser protective eyewear), and other appropriate signage are some of the methods to accomplish this requirement. Alternatively, an entryway warning light assembly may be interfaced to the laser in such a manner that one light will indicate when the laser is not operational (high voltage off) and by an additional light when the laser is powered up (high voltage applied, but no laser emission) and by an additional (flashing optional) light that activates when the laser is operating.

(*iv*) For class IV indoor controlled areas, during tests requiring continuous operation, the individual in charge of the controlled area shall be permitted to momentarily override the safety interlocks to allow access to other authorized personnel if it is clearly evident that there is no optical radiation hazard at the point of entry and if the necessary protective devices are being worn by the entering personnel.

(*v*) For class IV indoor controlled areas, optical paths (for example, windows) from an indoor facility shall be controlled in such a manner as to reduce the transmitted values of the laser radiation to levels at or below the appropriate ocular MPE and the limits listed in subsection (cc)(8) of this section. (When the laser beam must exit the indoor controlled area (as in the case of exterior atmospheric beam paths), the operator shall be responsible for ensuring that air traffic is protected from any laser projecting into navigable air space (contact Federal Aviation Administration (FAA) or other appropriate agencies, as necessary) or controlled ground space when the beam irradiance or radiant exposure is above the appropriate MPE and the limits listed in subsection (cc)(8) of this section).

(*vi*) When the removal of panels or protective covers and/or overriding of interlocks becomes necessary, such as for servicing, testing, or maintenance, and accessible laser radiation exceeds the MPE and the limits listed in subsection (cc)(8) of this section, a temporary controlled area shall be established and posted.

(s) Additional requirements for special lasers and applications.

(1) Infrared laser. The beam from a laser shall be terminated in fire-resistant material where necessary. Inspection intervals of absorbent material and actions to be taken in the event or evidence of degradation shall be specified in the operating and safety procedures.

(2) Laser optical fiber transmission system.

(A) Laser transmission systems that employ optical cables shall be considered enclosed systems with the optical cable forming part of the protective housing.

(B) Disconnection of a connector resulting in access to radiation in excess of the applicable MPE or the limits listed in subsection (cc)(8) of this section shall take place in a controlled area. Except for medical lasers whose manufacture has been approved by the FDA, the use of a tool shall be required for the disconnection of a connector for service and maintenance purposes when the connector is not within a secured enclosure. All connectors shall bear the appropriate label or tag specified in subsection (v)(3) of this section.

(t) Additional requirements for safe operation.

(1) Eye Protection. Protective eyewear shall be worn by all individuals with access to class IIIb and/or class IV levels of laser radiation. Protective eyewear devices shall meet the following requirements:

(A) provide a comfortable and appropriate fit all around the area of the eye;

(B) be in proper condition to ensure the optical filter(s) and holder provide the required optical density or greater at the desired wavelengths, and retain all protective properties during its use;

(C) be suitable for the specific wavelength of the laser and be of optical density adequate for the energy involved;

(D) have the optical density or densities and associated wavelength(s) permanently labeled on the filters or eyewear; and

(E) be examined, at intervals not to exceed 12 months, to ensure the reliability of the protective filters and integrity of the protective filter frames. Unreliable eyewear shall be discarded.

(2) Skin protection. When there is a possibility of exposure to laser radiation that exceeds the MPE limits for skin as specified in subsection (cc)(7) of this section, the registrant shall require the appropriate use of protective gloves, clothing, or shields.

(u) NHZ. Where applicable, in the presence of unenclosed class IIIb and class IV beam paths, an NHZ shall be established. If the beam of an unenclosed class IIIb or class IV laser is contained within a region by adequate control measures to protect personnel from exposure to levels of radiation above the appropriate MPE, that region may be considered to contain the NHZ. The NHZ may be determined by information supplied by the laser manufacturer, by measurement, or by using the appropriate laser range equation or other equivalent assessment.

(v) Caution signs, labels, and posting.

(1) General requirements. Except as otherwise authorized by the agency, signs, symbols, and labels prescribed by this section shall use the design and colors specified in subsection (dd)(1) and (2) of this section.

(2) Posting and instructions.

(A) The laser controlled area shall be conspicuously posted with an appropriate sign or signs as specified in paragraph (3) of this subsection and subsection (dd)(1) and (2) of this section.

(B) Operating personnel of each laser shall be provided with written instructions for safe use, including clear warnings and precautions to avoid possible exposure to laser and collateral radiation in excess of the MPE and the limits listed in subsection (cc)(8) of this section.

(3) Labeling lasers and posting laser facilities.

(A) Class IIIb lasers shall have a label and facilities shall be posted with a sign(s) with the warning specified in subsection (dd)(2) of this section that includes the following wording: "LASER RADIATION - AVOID DIRECT EXPOSURE TO BEAM. CLASS IIIb LASER (OR LASER PRODUCT)."

(B) Class IV lasers and facilities shall have a label affixed and be posted with a sign(s) with the warning specified in subsection (dd)(2) of this section that includes the following wording: "LASER RADIATION - AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION. CLASS IV LASER (OR LASER PRODUCT)."

(C) Lasers, except lasers used in the practice of medicine, shall have a label(s) in close proximity to each aperture through which is emitted accessible laser or collateral radiation in excess of the limits specified in subsection (cc)(5) and (8) of this section with the following wording as applicable.

(*i*) "AVOID EXPOSURE - Laser radiation is emitted from this aperture," if the radiation emitted through such aperture is laser radiation.

(*ii*) "AVOID EXPOSURE - Hazardous electromagnetic radiation is emitted from this aperture," if the radiation emitted through such aperture is collateral radiation.

(*iii*) "AVOID EXPOSURE - Hazardous x-rays are emitted from this aperture," if the radiation emitted through such aperture is collateral x-ray radiation.

(D) Each laser shall state, on the required warning logotype, the maximum output of laser radiation, the pulse duration when appropriate, and the laser medium or emitted wavelength(s).

(E) Each noninterlocked or defeatably interlocked portion of the protective housing or enclosure that is designed to be displaced or removed during normal operation or servicing, and that would permit human access to laser or collateral radiation, shall have labels as follows.

(*i*) For laser radiation in excess of the accessible emission limits of class IIIb, the wording: "DANGER - LASER RADIATION WHEN OPEN. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION."

(*ii*) For collateral radiation in excess of the emission limits of subsection (cc)(8) of this section:

(I) if the limits in subsection (cc)(8)(A) of this section are exceeded, the wording: "CAUTION - HAZARDOUS ELECTROMAGNETIC RADIATION WHEN OPEN"; and

(II) if the limits in subsection (cc)(8)(B) of this section are exceeded, the wording: "CAUTION - HAZARDOUS X-RAY RADIATION."

(*iii*) For protective housing or enclosures that provide a defeatable interlock, the words "and interlock defeated" shall be included in the labels specified in clauses (*i*) and (*ii*) of this subparagraph.

(F) Other required information.

(*i*) The word "invisible" shall immediately precede the word "radiation" on labels and signs required by this subparagraph for wavelengths of laser and collateral radiation that are outside of the range of 400 to 700 nm.

(*ii*) The words "visible and invisible" shall immediately precede the word "radiation" on labels and signs required by this subparagraph for wavelengths of laser and collateral radiation that are both within and outside the range of 400 to 700 nm.

(G) Labels required by this subparagraph shall be clearly visible, legible, and permanently attached to the laser or facility. Signs required by this subparagraph shall be clearly visible, legible, and securely attached to the facility.

(w) Surveys. Each registrant shall make or cause to be made such surveys as may be necessary to comply with this section. Surveys shall be performed at intervals not to exceed 12 months, to include but not be limited to the following:

(1) a determination that all laser protective devices are labeled correctly, functioning within the design specifications, and properly chosen for lasers in use;

(2) a determination that all warning devices are functioning within their design specifications;

(3) a determination that the laser controlled area is properly controlled and posted with accurate warning signs in accordance with subsection (v) of this section;

(4) a re-evaluation of potential hazards from surfaces that may be associated with laser beam paths; and

(5) additional surveys that may be required to evaluate the laser and collateral radiation hazard incident to the use of lasers.

(x) Records. Each registrant shall maintain current records in accordance with subsection (ee) of this section.

(y) Measurements and instrumentation. Each determination requiring a measurement for compliance with this section shall use instrumentation that is calibrated and designed for use with the laser that is to be tested.

(z) Notification of injury other than a medical event.

(1) Each registrant shall immediately seek appropriate medical attention for the individual and notify the agency by telephone of any injury involving a laser possessed by the registrant, other than intentional exposure of patients for medical purposes, that has or may have caused:

(A) an injury to an individual that involves the partial or total loss of sight in either eye; or

(B) an injury to an individual that involves perforation of the skin or other serious injury exclusive of eye injury.

(2) Each registrant shall, within 24 hours of discovery of an injury, report to the agency each injury involving any laser possessed by the registrant, other than intentional exposure of patients for medical purposes, that may have caused, or threatens to cause, an exposure to an individual with second or third-degree burns to the skin or potential injury and partial loss of sight.

(aa) Reports of injuries.

(1) Each registrant shall make a report in writing, or by electronic transmittal, within 30 days to the agency of any injury required to be reported in accordance with subsection (z) of this section.

(2) Each report shall describe the following:

(A) the extent of injury to individuals to laser radiation;

(B) power output of laser involved;

(C) the cause of the injury; and

(D) corrective steps taken or planned to be taken to prevent a recurrence.

(3) Any report filed with the agency in accordance with this subsection shall include the full name of each individual injured and a description of the injury. The report shall be prepared so that this information is stated in a separate part of the report.

(4) When a registrant is required in accordance with paragraphs (1)-(3) of this subsection to report to the agency any injury of an individual to laser radiation, the registrant shall also notify the individual. Such notice shall be transmitted to the individual at a time not later than the transmittal to the agency.

(bb) Medical event.

(1) The registrant shall notify the agency, by telephone or electronic transmittal, within 24 hours of any injury to or death of a patient. Within 30 days after a 24 hour notification is made, the registrant shall submit a written report to the agency of the event.

§289.301(bb)(2)

(2) The written report shall include the following:

(A) the registrant's name;

(B) a brief description of the event;

(C) the effect on the patient;

(D) the action taken to prevent recurrence; and

(E) whether the registrant informed the patient or the patient's responsible relative or guardian.

(3) When a medical event occurs, the registrant shall promptly investigate its cause, make a record for agency review, and retain the records as stated in subsection (ee) of this section.

(cc) Appendices.

(1) Class I accessible emission limits for laser radiation. The following table contains class I accessible emission limits for laser radiation.

Figure: 25 TAC §289.301(cc)(1)

(2) Class II accessible emission limits for laser radiation. The following table contains class II accessible emission limits that are identical to class I accessible emission limits except:

Figure: 25 TAC §289.301(cc)(2)

(3) Class IIIa accessible emission limits for laser radiation. The following table contains class IIIa accessible emission limits that are identical to class I accessible emission limits except:

Figure: 25 TAC §289.301(cc)(3)

(4) Class IIIb accessible emission limits for laser radiation. The following table contains class IIIb accessible emission limits for laser radiation.

Figure: 25 TAC §289.301(cc)(4)

(5) MPE for direct ocular exposure (intrabeam viewing) to a laser beam. The following table contains the MPEs for direct ocular exposure.

Figure: 25 TAC §289.301(cc)(5)

(6) MPE for viewing a diffuse reflection of a laser beam or an extended-source laser. The following table contains the MPEs for viewing a diffuse reflection of a laser beam or an extended source laser.

Figure: 25 TAC §289.301(cc)(6)

(7) MPE for skin exposure to a laser beam. The following table contains the MPEs for skin exposure to a laser beam.

Figure: 25 TAC §289.301(cc)(7)

(8) Accessible emission limits for collateral radiation from lasers or facilities and MPE. The following are accessible emission limits for collateral radiation from lasers or facilities and MPE.

(A) Accessible emission limits for collateral radiation having wavelengths greater than or equal to 180 nm but less than or equal to 1 mm are identical to the accessible emission limits of class I laser radiation as determined from subsection (cc)(1) of this section for the appropriate wavelength(s) and emission duration.

(*i*) In the wavelength range of $\leq$ 400 nm, for all emission durations.

(*ii*) In the wavelength range > 400 nm, for all emission durations less than or equal to 1×10^3 seconds and, when applicable for all emission durations.

(B) Accessible emission limit for collateral radiation within the x-ray range of wavelengths is 0.5 milliroentgen in an hour, averaged over an area of 10 square centimeters with no dimension greater than 5 centimeters.

(9) Values of wavelength dependent correction factors.

Figure: 25 TAC §289.301(cc)(9)

(10) Selected numerical solutions.

Figure: 25 TAC §289.301(cc)(10)

(11) Maximum aperture diameters (limiting aperture) for measurement averaging. The following table contains maximum aperture diameters (limiting aperture) for measurement averaging.

Figure: 25 TAC §289.301(cc)(11)

(A) This material is from American National Standard for the Safe Use of Lasers, ANSI Z136.1.

(B) For the specific case of optical viewing (beam collecting) instruments, the apertures listed for eye MPE and skin MPE apply to the exit beam of such devices.

(dd) Signs and graphs.

(1) Caution sign. The following sign contains an appropriate sign in accordance with subsection (v)(2)(A) of this section.

Figure: 25 TAC §289.301(dd)(1)

(2) Danger sign. The following sign contains an appropriate sign in accordance with subsection (v)(2)(A) of this section.

Figure: 25 TAC §289.301(dd)(2)

(3) Graph A. The following graph contains graphic representation in accordance with subsection (cc)(5) of this section.

Figure: 25 TAC §289.301(dd)(3)

(4) Graph B. The following graph contains graphic representation in accordance with subsection (cc)(5)-(7) of this section.

Figure: 25 TAC §289.301(dd)(4)

(5) Graph C. The following graph contains graphic representation in accordance with subsection (cc)(5)-(7) of this section.

Figure: 25 TAC §289.301(dd)(5)

(6) Graph D. The following graph contains graphic representation in accordance with subsection (cc)(6) of this section.

Figure: 25 TAC §289.301(dd)(6)

(7) Graph E. The following graph contains graphic representation in accordance with subsection (cc)(5)-(7) of this section.

Figure: 25 TAC §289.301(dd)(7)

(8) Graph F. The following graph contains graphic representation in accordance with subsection (cc)(5) and (6).

Figure: 25 TAC §289.301(dd)(8)

(9) Graph G. The following graph contains graphic representation in accordance with subsection (cc)(5) and (6) of this section.

Figure: 25 TAC §289.301(dd)(9)

(10) Graph H. The following graph contains graphic representation in accordance with subsection (cc)(5) and (6) of this section.

Figure: 25 TAC §289.301(dd)(10)

(ee) Record keeping. The following are time requirements for record keeping:

Specific Subsection	Name of Record	Time Interval Required for Record Keeping
(t)(1)(E)	Eye protection	5 years
(y)	Measurements and instrumentation	5 years
(z)	Notification of injury other than a medical event	5 years
(aa)	Reports of injuries	5 years
(bb)	Medical event	5 years